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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/088,951	06/02/1998	MARTIN A CHEEVER	920010.535	2326

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/04/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/088,951

Applicant(s)
Cheever et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-9, 11, and 12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-9, 11, and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 1, 7-9, 11 and 12 are under consideration.
3. The Declaration under 37 C.F.R. 1.131 filed on April 17, 2002 under 37 CFR 1.131 is sufficient to overcome the Chatta et al (Proc Am Assoc Cancer Res, 1997, Vol. 38, page 403) and Naftzger et al (PNAS, 1996, Vol. 93, pp. 14809-14814) references.

New Grounds of Rejection

4. Claims 1, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disis et al (Journal of Immunology, 1996 May, Vol. 156, pp. 3151-3158) in view of any of Dyrberg and Oldstone, (in: Current topic in Microbiology and Immunology, 1989, Vol. 130, pp. 25-37), or Mamula et al (Journal of Immunology, 1992, Vol. 149, pp. 789-795) or Fedoseyeva et al (Transplantation, 1996, Vol. 61, pp. 679-683) or Mahi-Brown (Journal of Reproductive Immunology, 1992, Vol. 21, pp. 29-46).

Disis et al teach that overcoming tolerance to self-tumor antigens is key in the generation of effective anti-tumor immunity. Disis et al teach a method for overcoming self tolerance to the Her-2/neu antigen by the administration of sub-dominant epitopes of rat Her-2/neu. Disis et al further teaches that immunization with intact rat Her-2/neu failed to elicit rat neu specific responses. Disis et al do not teach immunization of rats with Her-2/neu of another species or immunization of humans with her-2 from another species as a method for overcome tolerance to Her-2/neu. Dyberg and Oldstone teach the concept of "molecular mimicry" wherein autoimmunity to a host self protein can be induced by homologous but non-identical epitopes produced by viral infections. Mamula et al teach a method to induce an immune response to self cytochrome C in mice by immunizing with human cytochrome C or the immunodominant epitope of human cytochrome C consisting of residues 81-104. Fedoseyeva et al teach that transplantation of BALB/c mice (H2d) with splenocytes from allogenic BALB/c mice (H2a)

resulted in the recognition of the immunodominant self peptide Dd as tolerance to said self peptide was broken by the presentation of the cross reactive peptide Kk. Ruoslahti et al teach that mice immunized with zona pellucida antigens from rat or pig developed an immune response against self zona pellucida as evidenced by disrupted follicular development. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to immunize humans with intact rat neu protein. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Disis et al on requirement for breaking self-tolerance to tumor antigens in order to elicit an effective anti-tumor immune response, and on the further teachings of Dyberg and Oldstone, Mamula et al, Fedoseyeva et al or Ruoslahti et al on the concept of overcoming self-tolerance by presenting to a host a homologous but non-identical protein. None of the references specifically teach an 80% amino acid identity to the self protein, but said level of identity would be inherent in the homologous proteins taught by the prior art.

5. Claims 1, 7-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disis et al (Journal of Immunology, 1996 May, Vol. 156, pp. 3151-3158) and Dyrberg and Oldstone, (in: Current topic in Microbiology and Immunology, 1989, Vol. 130, pp. 25-37), and Mamula et al (Journal of Immunology, 1992, Vol. 149, pp. 789-795) and Fedoseyeva et al (Transplantation, 1996, Vol. 61, pp. 679-683) and Mahi-Brown (Journal of Reproductive Immunology, 1992, Vol. 21, pp. 29-46) as applied to claims 1, 7, 8, 11 and 12 above, and further in view of Spitler et al (US 5,925,362).

For the reasons stated above, the combination of Disis et al and Dyrberg and Oldstone, and Mamula et al and Fedoseyeva et al and Mahi-Brown render obvious the methods of claims 1, 7, 11 and 12. Neither Disis et al nor Dyrberg and Oldstone, nor Mamula et al nor Fedoseyeva et al nor Mahi-Brown teach an antigen associated with prostate cancer or PAP.

Spitler et al teach a method to elicit an immune response in humans by vaccination with human tumor antigens such as PSA, PAP, PMSA and adjuvant. Spitler et al teach that human PSA expressed recombinantly in insect cells result in post-translationally modified PSA which has

different immunogenicity from PSA recombinantly expressed in human cells (column 5, lines 54-59). Spitler et al do not teach a method to elicit or enhance an immune response to by immunization with a xenogeneic protein homologous to PSA or PAP. However, for the specific reasons stated above, any of Dyberg and Oldstone, Mamula et al, Fedoseyeva et al or Ruoslahti et al teach the concept of inducing immunity to self antigens in a host by presenting to said host a homologous but non-identical protein. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to elicit or enhance an immune response to human PSA or PAP by immunization with a xenogeneic protein homologous to PSA or PAP. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Dyberg and Oldstone, Mamula et al, Fedoseyeva et al or Ruoslahti et al on the concept of inducing immunity to self antigens in a host by presenting to said host a homologous but non-identical protein. None of the references specifically teach an 80% amino acid identity to the self protein, but said level of identity would be inherent in the homologous proteins taught by the prior art.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Carson et al (US 5,679,647).

Carson et al disclose a method of eliciting an immune response to a human self-tumor antigen comprising administering a polynucleotide which expresses a polypeptide from a non-human source, wherein said polypeptide mimics said human self-tumor antigen but is not identical to the human self-tumor antigen (column 27, lines 6-13, column 29, lines 56-64, claims 1 and 8). Carson et al further disclose organ-specific tumor associated antigens such as prostate-specific transmembrane protein (column 21, lines 42-61) as suitable targets for the disclosed method.

8. Claims 1, 7-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al (US 5,679,647) in view of Laus et al (US 6,080,409).

Carson et al do not teach prostatic acid phosphatase as a tumor associated antigen. Laus et al teach prostatic acid phosphatase as a tumor associated antigen.

Laus et al teach a method of stimulating an immune response comprising the administration of dendritic cells pulsed with peptides obtained from prostatic acid phosphatase (column 14, example 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the polynucleotide encoding prostatic acid phosphatase for the polynucleotide encoding prostate-specific transmembrane protein in the method taught by Carson et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Laus et al on the efficacy of administering dendritic cells pulsed with peptides of prostatic acid phosphatase as a method of inducing cytotoxic T-cell response in vivo.


9. Applicant argues that it is not permissible to combine the reference of Disis et al in a 103 rejection as Disis et al used peptide fragments of Her-2 neu to overcome the tolerance to the Her-2/neu antigen rather than intact Her-2/neu from a second species. This has been considered but not found persuasive. Disis et al teach the need to overcome self-tolerance in order to generate

an effective anti-tumor response. To this end, the references of Dyrberg and Oldstone,, and Mamula et al and Fedoseyeva et al and Mahi-Brown all teach the administration of a homologous peptide obtained from a second species as a means to overcome self-tolerance in a first species. As these references teach a method for overcoming self-tolerance, it is appropriate to combine then with the Disis et al reference which teaches the need to over come self-tolerance.

10. All other rejections and objections as stated in Paper No. 24 are withdrawn.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


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Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
June 3, 2002